

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
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SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
 )  
v. )  
 )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8378

Bartle, C.J.

January 7, 2010

Alex Pareigis ("Mr. Pareigis" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February 2003, Mr. Pareigis submitted a completed Green Form to the Trust signed by his attesting physician, Stephen Raskin, M.D., F.A.C.C. Based on an echocardiogram dated August 22, 2002, Dr. Raskin attested in Part II of claimant's Green Form that claimant suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial

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describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension.<sup>3</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$486,424.<sup>4</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Helbert V. Acosta, M.D., observed that claimant had a moderate mitral regurgitation ratio of 34%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In September 2005, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In audit, Dr. Wang concluded that claimant had mild mitral regurgitation and that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In support of this determination, Dr. Wang opined that "[t]he RJA was overtraced and the LAA is understated because the frame selected for tracing is foreshortened."

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3. Dr. Raskin also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying the claim of Mr. Pareigis. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>5</sup> In contest, claimant submitted a declaration from Dr. Raskin, who, upon reexamination of claimant's echocardiogram, asserted that: (1) claimant's echocardiogram study did not include excessive color gain or an inappropriately low Nyquist limit; (2) planimetry of the LAA excluded pulmonary vein flow; and (3) Dr. Wang's differing measurement of the RJA demonstrated "inconsequential inter-reader variability." Dr. Raskin also attached to his declaration three frames from claimant's echocardiogram in which moderate mitral regurgitation was purportedly demonstrated. Claimant argued that Dr. Raskin's declaration provided a reasonable medical basis for his claim.

The Trust then issued a final post-audit determination, again denying the claim of Mr. Pareigis. In its letter, the Trust asserted that Dr. Raskin's declaration does nothing to refute the findings of the auditing cardiologist. Specifically, the Trust noted that Dr. Raskin's finding of appropriate settings

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4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the claim of Mr. Pareigis.

for color gain and Nyquist limit in claimant's echocardiogram does nothing to refute Dr. Wang's conclusion that the RJA was overtraced to include non-regurgitant flow. The Trust further averred that Dr. Raskin's argument relating to the concept of inter-reader variability does not account for Dr. Wang's finding that the RJA was overtraced to include non-regurgitant flow. Moreover, the Trust contended that Dr. Raskin admitted in his declaration to relying upon an underestimated LAA.

Claimant disputed this final determination and requested that his claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim of Mr. Pareigis should be paid. On March 6, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6039 (Mar. 6, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>6</sup> to review claims after the Trust and

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Mr. Pareigis has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Pareigis asserts that the Trust improperly dismissed the declaration of Dr. Raskin, who, according to claimant, carefully explained why the echocardiogram

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critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

settings for color gain and Nyquist limit were relevant to whether the RJA was overtraced. Claimant further argues that Dr. Raskin did not ascribe Dr. Wang's conclusions entirely to inter-reader variability, but rather determined that the variation regarding the RJA was inconsequential. Finally, claimant contends that the Trust misconstrued Dr. Raskin's acknowledgment that the LAA was underestimated by failing to account for the attesting physician's conclusion that the level of mitral regurgitation was still within the definition of moderate mitral regurgitation even assuming such an underestimated LAA.

In response, the Trust reasserts the arguments addressed in the final post-audit determination, and further avers that "[e]chocardiogram settings and planimetry are not, as Dr. Raskin suggests, one and the same, and a regurgitant 'jet' can be overtraced by the sonographer or cardiographer regardless of the echocardiogram settings employed." The Trust concludes that relying upon an overtraced RJA and an underestimated LAA are beyond the bounds of medical reason and cannot support a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Burke remarked in his Report:

Using representative beats in the apical four chamber view, I calculated the RJA/LAA (regurgitant jet area/left atrial area) ratios to range from 13 to 26%. This represents mild to moderate mitral regurgitation.

Using representative beats in the apical two chamber view, I calculated RJA/LAA ratios to range from 22 to 26%. This represents moderate mitral regurgitation.

Using representative beats in the apical three chamber view, I calculated RJA/LAA ratios to range from 22 to 34%.

Although I agree with Dr. Wang that (in the frame selected on the tape for tracing RJA and LAA ratio) the RJA was overtraced and the LAA was undertraced, I believe that the mitral valve regurgitation was still in the moderate range both by my global assessment as well as by my calculations listed above.

In conclusion, I believe there is a reasonable basis for the Attesting Physician's answer to Green Form Question C.3.a., which states that Claimant suffers from moderate mitral regurgitation.

In response to the Technical Advisor Report, claimant argued that he was entitled to Matrix A, Level II benefits based on the auditing cardiologist's finding of an abnormal left atrial dimension and the Technical Advisor's finding of moderate mitral regurgitation.

After reviewing the entire show cause record before us, we find that claimant has established a reasonable medical basis for his claim. Claimant's attesting physician, Dr. Raskin, reviewed claimant's echocardiogram twice and found that claimant had moderate mitral regurgitation. Although the Trust challenged the attesting physician's conclusion, Dr. Burke confirmed the

attesting physician's finding of moderate mitral regurgitation.<sup>7</sup> Specifically, Dr. Burke concluded that "there is a reasonable basis for the Attesting Physician's answer to Green Form Question C.3.a., which states that Claimant suffers from moderate mitral regurgitation."

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Burke found that claimant's RJA/LAA ratio was greater than 20% in the apical two chamber, apical three chamber and apical four chamber views. Under these circumstances, claimant has met his burden in establishing a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has met his burden in proving that there is a reasonable medical basis for his claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Mr. Pareigis for Matrix Benefits.

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7. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.